

Director, Regulatory Affairs (Digital Medical Devices)

Job ID
REQ-10064222

3月 17, 2026

United Kingdom

摘要

Office Location: London (The Westworks), United Kingdom
#LI-Hybrid (12 days per month on-site if living within 50 miles to our London office)
#LI-Remote (if living beyond 50 miles to our London office)

We're looking for a seasoned regulatory expert to lead global strategy and execution for digital medical devices, including Digital Health Technologies (DHTs) and Software as a Medical Device (SaMD). This role drives regulatory direction across development, registration, and post-approval, ensuring timely, compliant decisions that balance patient safety and business needs.

About the Role

Major accountabilities:

- Develop and communicate digital medical device regulatory strategies for projects across the

life cycle (Development and On-Market).

- Ensure digital device regulatory risks and key issues are communicated in a timely manner to project teams and other stake holders. Represent de-department in cross-functional project teams as appropriate.
- Provide Novartis technical and clinical functions clear, concise guidance on current digital device regulatory requirements to support planning and decision making.
- Lead and implement global digital device submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products
- Lead the identification of the required documentation and content, compliance and timelines issues for global digital device submissions and work collaboratively with cross-functional teams for the delivery of technical source documents in accordance with project timelines.
- Author and/or review compliant digital device documentation for HA submissions, applying agreed digital device global regulatory strategies, current regulatory standards and guidelines.
- Lead, prepare and communicate digital device risk management assessments, contingency plans, and lessons learned on major submissions and escalate as appropriate.
- Drive digital device related interactions with Health Authorities globally.
- Knowledge sharing, e.g. provide coaching within Regulatory Affairs and other functional areas.
- Development of new digital device regulatory guidance, policy, and processes.

Minimum requirements:

- Science Degree (e.g. Engineering, Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent.
- Significant experience in the digital device industry or regulatory agency with responsibility for digital devices.
- Significant knowledge/experience in digital device regulatory submission and approval processes.
- Demonstrated practical experience in digital device regulatory affairs (e.g. IDE/510(k)/PMA filings; application of digital device quality management systems, software validation, human factors, design verification/validation requirements).
- Experience of leading regulatory health authority interactions, inspections and/or external advocacy/regulatory policy.
- Ability to critically evaluate data from a broad range of scientific disciplines.
- Knowledge of digital device development and life cycle management.
- Ability to work independently and successfully with global project teams and prioritize activities considering timelines and workload.

Commitment to Diversity & Inclusion

Novartis is committed to building an outstanding, inclusive work environment and diverse team 's representative of the patients and communities we serve.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally. [Read our handbook \(PDF 30 MB\)](#)

部门

Development

Business Unit

Development

地点

United Kingdom

站点

London (The Westworks)

Company / Legal Entity

GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1

Home Worker, United Kingdom

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

```
function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =
document.getElementById("kalturaplayer69c04abb2c48c979865099"); var mediaContainer =
mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px";
var originalWidthValue = parseFloat(originalWidth); var originalHeightValue =
parseFloat(originalHeight); var mediaType = "video"; var isResponsive = false; // Get computed styles
of the container element. var parentStyles = window.getComputedStyle(mediaContainer); var
finalWidth = parseFloat(parentStyles.width); if (finalWidth < deviceWidth) { var config = { targetId:
"kalturaplayer69c04abb2c48c979865099", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false,
allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: { download: {
disable: true }, "playkit-js-transcript":{ position: "right", // Default: bottom;( ' left ', ' right', ' top ', 'bottom' ) to
enable transcript. expandMode: "over", // Default: alongside;( ' alongside', ' hidden ', 'over' )
expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable:
true } }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false },
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; config.plugins.preventSeek = { preventSeekForward:
false, preventSeek: false }; config.plugins.floating = { disable: true }; config.plugins.navigation = {
position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; config.plugins['playkit-
js-hotspots'] = { disable: true }; config.plugins['playkit-js-moderation'] = { disable: true };
config.plugins['playkit-js-info'] = { disable: true }; config.plugins.share = { disable: true };
config.ui.uiComponents = []; config.plugins.googleTagManager = {};
config.plugins.googleTagManager.customEventsTracking = {};
config.plugins.googleTagManager.containerId = 'GTM-57RJQ5';
config.plugins.googleTagManager.customEventsTracking.custom = [];
config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents:
false, playlistEvents: false, castEvents: false } } };
```

```
try { var kalturaPlayer = KalturaPlayer.setup(config); // Add the player to the global array. if (typeof
kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var
kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other
media. kalturaPlayer.loadMedia({entryId: "1dgfvmafo"}); setTimeout(() => {
setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) {
players.forEach((currentPlayer) => { currentPlayer.addEventListener('play', () => {
players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause ===
'function') { otherPlayer.pause(); } })); }); }); } catch (e) { console.error(e.message) }
```



VIDEO

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10064222

Director, Regulatory Affairs (Digital Medical Devices)

[Apply to Job](#)



Job ID
REQ-10064222

Director, Regulatory Affairs (Digital Medical Devices)

[Apply to Job](#)

Source URL:

<https://prod1.novartis.com.cn/careers/career-search/job/details/req-10064222-director-regulatory-affairs-digital-medical-devices>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://www.novartis.com/sites/novartis.com/files/novartis-life-handbook.pdf>
3. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/London-The-Westworks/Director--Regulatory-Affairs--Medical-Devices-REQ-10064222-1>
4. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/London-The-Westworks/Director--Regulatory-Affairs--Medical-Devices-REQ-10064222-1>